

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S, )  
                            )  
Plaintiff,             )  
                            )  
v.                         )                           C.A. No. 05-614 (SLR)  
                            )  
ACAMBIS INC. and        )  
ACAMBIS PLC,            )  
                            )  
Defendants.             )  
                            )

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**OPENING BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR  
LEAVE TO FILE AMENDED ANSWER AND COUNTERCLAIMS**

MORRIS, NICHOLS, ARSH & TUNNELL LLP  
Mary B. Graham (#2256)  
James W. Parrett, Jr. (#4292)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200

*Attorneys for Defendants  
Acambis Inc. and Acambis plc*

OF COUNSEL:

William D. Coston  
Lindsay B. Meyer  
Eric S. Namrow  
Martin L. Saad  
VENABLE, LLP  
575 7<sup>th</sup> Street, NW  
Washington, DC 20004-1601  
(202) 344-4000

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## **INTRODUCTION**

Pursuant to Rules 15(a) and (d) of the Federal Rules of Civil Procedure, defendants Acambis Inc. and Acambis plc (“Acambis”) are requesting leave to amend their Answer and add seven counterclaims. Pursuant to D. Del. L.R. 15.1, attached as Exhibit 1 to the motion are two copies of Acambis’ proposed amended pleading, and attached as Exhibit 2 to the motion is a copy indicating the respects in which the amended pleading differs from the original pleading. The bases for the motion are as follows:

## **STATEMENT OF FACTS**

### **A. Procedural History.**

On August 19, 2005, Bavarian Nordic A/S (“BN”) filed both this action and a complaint with the ITC. (D.I. 1). Acambis answered BN’s complaint on September 8, 2005. (D.I. 6). On September 19, 2005, the ITC instituted an investigation into the allegations raised by BN’s ITC complaint. In light of the identical allegations raised both in this Court and the ITC, Acambis moved to stay this case on October 4, 2005. (D.I. 12).

The Court in this case entered a scheduling order on October 26, 2005. (D.I. 20). Fact discovery is to be completed by August 14, 2006 and expert discovery is to be completed by November 3, 2006. This case is scheduled for a two week jury trial beginning on June 5, 2007. While the parties have exchanged discovery in this case, the vast majority of discovery has been taken in the context of the parallel ITC proceeding. The parties have tentatively agreed that discovery from the parties in the ITC proceeding also may be used in this case.

Fact discovery in the parallel ITC action was completed on February 20, 2006, and expert discovery was completed on March 10, 2006. A six-day evidentiary hearing before

the ALJ on the patent infringement claims – the only claims remaining in the ITC action and a primary basis for the proposed counterclaims in this case – began on May 8, 2006. Acambis has taken the position at the ITC trial that the patents-in-suit are invalid on a number of grounds, including anticipation and inventorship errors, and that the patents are unenforceable due to BN's inequitable conduct before the patent office.

Following post-trial briefing by the parties in the ITC proceeding, the ALJ is scheduled to issue an initial determination by August 24, 2006. The ITC is scheduled to issue a final determination in that action by November 24, 2006.

**B. The Proposed Amendments and Counterclaims.**

Acambis seeks to amend its Answer to add that BN's trade secret claim is subject to mandatory and binding arbitration and to add factual bases to its affirmative defense of inequitable conduct. Acambis also seeks to add declaratory judgment counterclaims of patent invalidity and unenforceability.

In addition, Acambis seeks to add a third and fourth counterclaim that allege Sherman Act violations of *Walker Process* fraud and sham litigation. These counterclaims are based on BN's illegal efforts to monopolize the market for MVA-based smallpox vaccines and prevent Acambis from selling its MVA-based smallpox vaccine to the U.S. Government. As set forth in the proposed counterclaims, BN has sought to effectuate its illegal scheme through baseless litigation against Acambis in the U.S. International Trade Commission ("ITC") and in this Court based on fraudulently procured and clearly invalid patents and other unsupported theories. Through such litigation and other illegal conduct, BN has, among other things, sought to interfere with Acambis' ability to bid on, procure, and fulfill contracts offered by the U.S. Government, artificially decreased the value of Acambis stock, damaged Acambis' reputation and good will, and cost Acambis millions of dollars in litigation fees and costs. Through this

action, Acambis seeks a declaratory judgment of invalidity and unenforceability of BN's patents and recompense for the damage caused by BN's illegal conduct.

Acambis learned in the course of discovery in the ITC action of important facts that form the basis for these claims, including: (1) the true origin and history of the strain claimed in the patent; (2) the true role of the named inventors on the patents; (3) the true facts underlying the single experiment that is the basis for the patents in suit; and (4) the facts underlying BN's claim to a "property" right in the virus underlying MVA3000. As to each of these facts, it is evident that BN knowingly made false representations to the patent office or in its pleadings.

A fifth counterclaim alleges tortious interference with contracts and business expectations and the sixth alleges Lanham Act violations, and a seventh alleges violations of the Delaware Deceptive Trade Practices Act and common law of unfair competition.

## **ARGUMENT**

### **I. Applicable Law.**

Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend "shall be freely given when justice so requires" and, as the Supreme Court has declared, "this mandate is to be heeded." Fed. R. Civ. P. 15(a); *Foman v. Davis*, 371 U.S. 178, 182 (1962). "If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." *Id.* As such, Rule 15(a) embodies the liberal pleading philosophy of the federal rules. *Adams v. Gould Inc.*, 739 F.2d 858, 864 (3d Cir. 1984). This liberal amendment philosophy limits the district court's discretion to deny leave to amend. *Id.* A court may only deny a motion for leave to amend if it finds undue

delay in bringing the amendment, undue prejudice to the non-moving party, bad faith or a dilatory motive on the part of the movant, or a failure to state a cause of action. *See id.*

Similarly, under Fed. R. Civ. P. 15(d), a party may move for leave to supplement its pleading “upon reasonable notice and upon such terms as are just” in order to “set[] forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented.” The underlying purpose of Rule 15(d) is to “to promote as complete an adjudication of the dispute between the parties as possible” and, in this way, to enhance judicial economy. *Coca-Cola Bottling Co. of Elizabethtown, Inc. v. Coca-Cola Co.*, 668 F. Supp. 906, 922-23 (D. Del. 1987). Leave to supplement the pleadings, like leave to amend, should be granted unless it causes undue delay or undue prejudice. *See Medeva Pharma Ltd. v. Am. Home Prods. Corp.*, 201 F.R.D. 103, 104 (D. Del. 2001). Indeed, the standard for supplementation under Rule 15(d) is essentially the same as the standard for amendments under Rule 15(a), *id.* at 104 n.3, and thus leave to supplement under Rule 15(d) “should, consistent with the command of Rule 15, be liberally granted,” *Thomas v. SmithKline Beecham Corp.*, No. 00-2948, 2002 WL 32351172, at \*2 (E.D. Pa. 2002). Because the 15(a) and (d) standards are the same, Acambis will provide a combined analysis.

## **II. There Has Been No Undue Delay.**

“Well-established precedent in the Third Circuit dictates that delay, in and of itself, is an insufficient basis for denial of a motion to amend.” *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 125 F.R.D. 405, 408 (D. Del. 1987). To justify a denial of a motion to amend or supplement, the delay must be “undue.” *See Adams*, 739 F.2d at 868. Here there has been no undue delay. Acambis has timely brought its motion to amend after learning the facts and circumstances of BN’s activity, including its fraudulent conduct, uncovered through

discovery in this case and the parallel ITC proceeding, which the parties have agreed may be used in this case.

### **III. Bavarian Nordic Will Not Be Prejudiced.**

In opposing this motion, BN bears the burden of proving that actual prejudice would result if Acambis were granted leave to amend and supplement. *See Pegasus Dev. Corp. v. DirecTV, Inc.*, Civ. No. 00-1020-GMS, 2002 WL 598457, at \*2 (D. Del. 2002). To carry its burden, BN cannot merely *claim* prejudice; it must show that it has been unfairly disadvantaged or deprived of the opportunity to present facts or evidence that could have been presented had the amendments been made earlier. *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989). Undue prejudice does not result from delay in the movement of a case or from the need to incur additional legal fees. *Pegasus*, 2002 WL 598457, at \*2. Thus, the need for additional discovery does not generally generate the type of undue prejudice that would foreclose an amendment or supplementation under Rule 15. *See CenterForce Tech., Inc. v. Austin Logistics Inc.*, Civ. No. 99-243-MMS, 2000 WL 652943, at \*6 (D. Del. 2000); *see also Jenn-Air Prods. Co. v. Penn Ventilator, Inc.*, 283 F. Supp. 591, 594 (E.D. Pa. 1968) (“[P]rejudice ordinarily is not considered to have occurred unless the motion is made during or after the actual trial.”).

BN cannot demonstrate prejudice, undue or otherwise. Currently, the parties are in the discovery period and have taken discovery both in this action and in the parallel ITC action. This litigation has not progressed far enough that there could be any prejudice resulting from adding Acambis’ counterclaims.

### **IV. Acambis Does Not Seek Leave to Amend and Supplement in Bad Faith or With a Dilatory Motive.**

Acambis does not bring this motion in bad faith or with a dilatory motive. As explained above, Acambis only learned the full extent of the facts underlying BN’s fraudulent

activities through discovery in this case and the parallel ITC proceeding. Acambis could not have been expected to bring those counterclaims any sooner. Acambis needed discovery from BN in order to fully articulate the basis for its new counterclaims. Now that it has discovered the necessary factual basis, Acambis timely seeks to amend its answer to add additional counterclaims based on information uncovered during discovery.

**V. The Proposed Amendments and Supplementation Are Not Futile.**

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There is no basis to argue that Acambis' proposed amendments and supplementations are futile. Acambis' proposed pleading states claims upon which relief could be granted under Fed. R. Civ. P. 12(b)(6), *e.g.*, fraud, patent invalidity and antitrust violations, and thus the amendments and supplementations are not futile. *See Adams*, 739 F.2d at 864-66.

**CONCLUSION**

For all of the foregoing reasons, defendants Acambis Inc. and Acambis plc request that their Motion For Leave To File Defendants' Amended Answer And Counterclaims be granted.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ James W. Parrett, Jr. (#4292)*

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Mary B. Graham (#2256)  
James W. Parrett, Jr. (#4292)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200

*Attorneys for Defendants  
Acambis Inc. and Acambis plc*

OF COUNSEL:

William D. Coston  
Lindsay B. Meyer  
Eric S. Namrow  
Martin L. Saad  
VENABLE, LLP  
575 7<sup>th</sup> Street, NW  
Washington, DC 20004-1601  
(202) 344-4000

Dated: May 22, 2006  
521174

**CERTIFICATE OF SERVICE**

I hereby certify that on May 22, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

John W. Shaw, Esquire  
YOUNG CONAWAY STARGATT & TAYLOR LLP  
The Brandywine Building, 17<sup>th</sup> Floor  
1000 West Street  
Wilmington, DE 19801

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on May 22, 2006 upon the following individuals in the manner indicated:

**BY HAND**

John W. Shaw, Esquire  
YOUNG CONAWAY STARGATT & TAYLOR LLP  
The Brandywine Building, 17<sup>th</sup> Floor  
1000 West Street  
Wilmington, DE 19801

**BY FEDERAL EXPRESS (5/23/06)**

Edward A. Pennington  
SWIDLER BERLIN LLP  
3000 K Street, Suite 300  
Washington, DC 20007

*/s/ James W. Parrett, Jr. (#4292)*  
\_\_\_\_\_  
James W. Parrett, Jr. (#4292)